EASY-CARE Trial: Participant Information Sheet

Hospital Site: University College London Hospital
Trial Sponsors: Sola Diagnostics.com
Funders: National Institute for Health and Care Research
Trial Website: www.easy-care.org
Or Click on QR code for further information

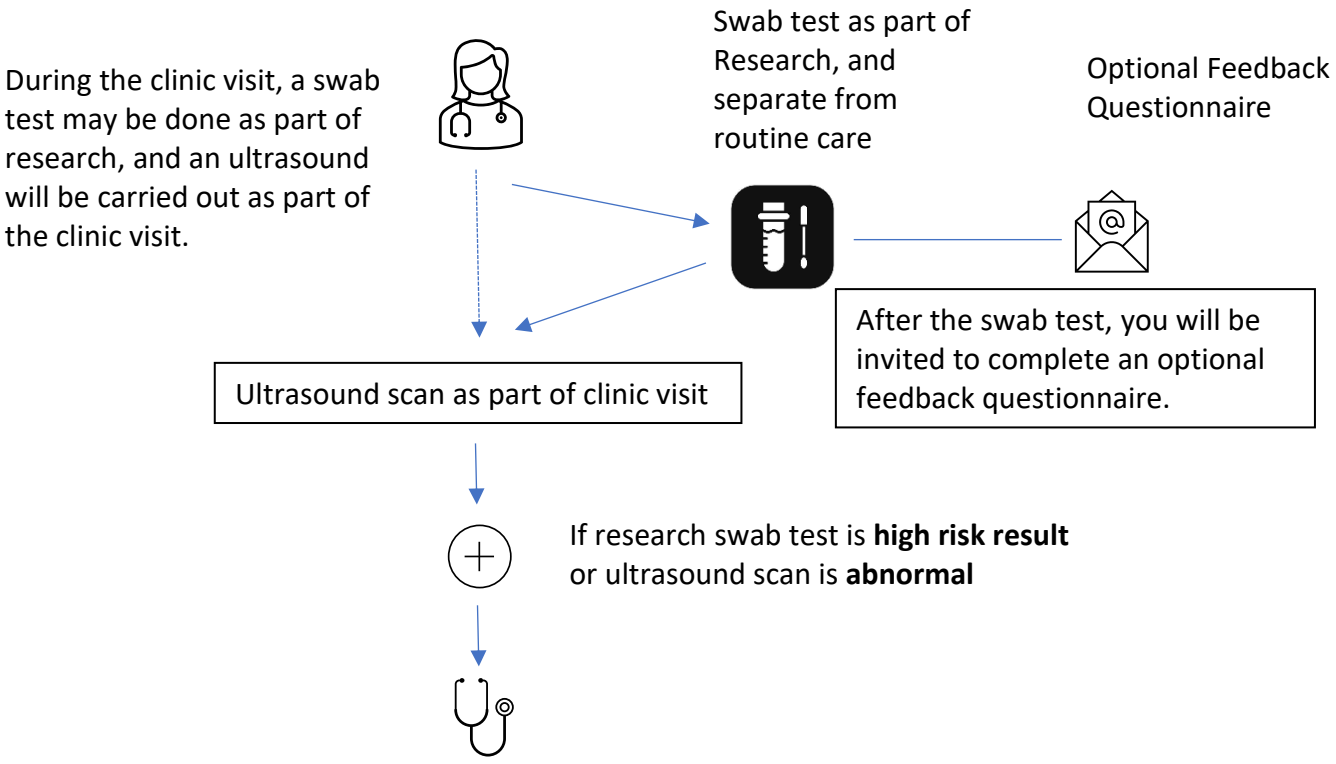
Would you like to be part of a trial looking at a new test for Womb Cancer?

We would like to invite you to take part in a research trial. Before you decide we would like you to understand why the research is being done and what it will involve for you.

One of our research team will go through the information sheet with you and answer any questions you have.

Please take time to read the following information carefully and discuss it with family & friends if you wish.

See below for a summary diagram of participation in the EASY-CARE Study.



What is the purpose of the study?

Womb cancer (also known as endometrial cancer) is a common type of cancer that affects the womb lining. The main symptom of womb cancer is abnormal vaginal bleeding. However, only a small proportion of women with abnormal bleeding have womb cancer. Unfortunately, there are challenges in diagnosing womb cancer early. Ultrasound scans are often not specific enough, leading to many women being referred for further invasive tests unnecessarily.

The WID®-easy test looks for specific changes in the DNA, or Deoxyribonucleic Acid, in a cervicovaginal sample. DNA carries the genetic instructions for our bodies and is like a biological "blueprint." The WID®-easy test is designed to detect changes in specific parts of the DNA associated with womb cancer.

A cervicovaginal sample refers to use of the swab to collect fluid from the top of the vagina and around the cervix. The sample is taken by a healthcare professional using a simple cotton swab during your routine examination.

Previous studies have shown the WID®-easy test to be as good as an ultrasound at detecting womb cancer and would reduce the number of women who need further invasive tests. This research project aims to compare the performance of the ultrasound scan and the WID®-easy test and to gather the information needed to support the introduction of the WID®-easy test throughout the NHS. We will conduct a large study in 2,000 women referred to a hospital clinic because of abnormal uterine bleeding. You will be requested to give a sample for the WID®-easy test and then you will also receive the tests and care you would normally receive.

Do I have to take part?

No. You are free to decide. We will tell you about the study and if you decide to take part, please keep this information sheet. If you decide to take part and then change your mind, you can withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

You can withdraw at any time by emailing Professor Davor Jurkovic, Email: EASYCAREteam@nhs.net. If your sample has not been processed it will be destroyed by the laboratory. In the case that the sample has been processed, any stored leftover sample will be destroyed.

During this research, new information may become available about the test. In this case, we will contact you will have the opportunity to ask questions and discuss any concerns with a member of the research team. If you decide not to continue, your decision will be respected and will not affect the care you receive.

What will happen to me if I take part?

You will be invited to take part in trial study during your clinic visit. If you wish to hear more about the trial this can be explained to you during your appointment. You will be given the opportunity to ask questions. If you wish to participate, you will be asked to sign a consent form.

We will need to collect a sample from you. This will be a cervicovaginal swab collected by the doctor seeing you during your pelvic examination. Following this examination, you will have your appointment as normal.

If you choose to participate in this research, it will require an extra 15–20 minutes during your clinic appointment.
You will then carry on having your usual routine appointment Your doctor will advise you about other tests or procedures they feel you need based on your ultrasound scan results.

The swab will be analysed after your clinic appointment. If your swab test comes back positive, you will be contacted and asked to come back to have a hysteroscopy during a second appointment, which takes approximately 30 minutes. This is a camera test to look inside the womb and take a biopsy. You may have already been advised to have a biopsy or hysteroscopy based on your ultrasound results during your first appointment. If this is the case, no additional tests will be required based on a high risk WID®-easy test. Only a very small number of women who have a high risk WID®-easy swab will be asked to come back for tests which they had been told were not necessary based on their ultrasound scan.

In this case, you would be advised to have the hysteroscopy and biopsy under general anaesthetic (asleep) so that the most reliable biopsy could be taken. If there was a medical reason why you could not have a general anaesthetic, or you preferred not to have one, you would be given the option of having these tests under sedation (not fully asleep) or with an injection in your back to make sure you were unable to feel anything during the procedure. This would be fully discussed with you by the doctors looking after you and it would be your choice whether to have these additional tests and what sort of anaesthetic to have.

Occasionally, the WID®-easy test may report an inconclusive result. If your swab test is inconclusive, we will invite you back for a repeat test.

You will not have to pay for any part of this study. The research procedures (such as sample collection and testing) are provided at no cost to you. You will receive £20 voucher for any additional visits that are not part of your routine care.

Your medical records will be accessed by the clinical team who are also part of the research team for this trial. Routine clinical data needed for your NHS appointment will be collected by this team who will also ask you some additional questions as part of the research trial. At enrolment to the trial, personal identifiers such as your name, date of birth and hospital number will be removed, and you will be assigned a unique ID number. Data relating to you will be entered on a protected study database and it will not be possible to identify you from the research data collected.

The pathology lab is an NHS-accredited lab which means that they test routine hospital samples. The lab personnel who analyse your swab sample will have access to your personal details (Name & Date of Birth & Hospital Number) for management of your results. The lab personnel will not have access to the study database or any information contained within it.

We will keep a record of your scan findings, as well as findings from any further investigations you may need to have such as a biopsy or camera test (hysteroscopy).

We will collect additional data from your medical records at 3 months and 12 months to gather any outcome data. We will also use National Cancer Registration Analysis Service (NCRAS) data as another way of checking whether you have been diagnosed with a cancer during the 12 months after participating in this study.

Additional Optional Feedback

We may also ask you to complete a short questionnaire about your experience as well as your thoughts and opinions regarding the potential of cervicovaginal sampling as a means of testing for cancer in the future

There will also be an opportunity to give 1:1 interview feedback with our research collaborators on this trial and they are based at University College London (UCL) Partners. UCL Partners have expertise in conducting research to collect and analyse data on participant feedback and experiences.

Separate further information will be provided by the research team if you are interested to take part in the interviews.

What if I choose not to take part?

The usual, standard tests will be carried out anyway, and your care won't be affected.

What are the benefits of taking part?

The direct benefit of taking part in this research is that the WID®-easy test has the potential to detect any womb cancers that may be missed by ultrasound, which is the current standard test you would be offered for investigation of abnormal bleeding
If successful, this project could provide a less invasive way to detect womb cancer with fewer women needing invasive tests across the NHS.

What are the possible disadvantages and risks of taking part?

When the doctor takes the sample for the WID®-easy test, you may experience a similar discomfort to a cervical screening smear test. No other risks are anticipated with the WID®-easy test, however, there could be an extremely rare possibility that unanticipated risks might occur, as this is a research study of a new test. If any new information about risks becomes known during the study, you will be informed promptly.

If your WID®-easy test shows a high risk result, or if your ultrasound scan is abnormal, then additional tests may be recommended which have their own potential risks. A high risk WID®-easy test result suggests an increased chance of cancer. The clinical team will discuss further what this may mean for you if your test comes back as high risk result.

With any diagnostic test, including ultrasound which is the current standard of care test, there is a small risk of getting a false result. If you have a false negative result, we anticipate that you would continue to have symptoms and would return to clinic and be reassessed. If you have a false positive result, you will have had an additional test to determine whether you have cancer.

What will happen to the sample I provide?

Your collected cervicovaginal sample will be sent to an NHS pathology laboratory for analysis using the WID®-easy test, which looks for specific changes in DNA. This is done using a technique that detects whether a specific part of the DNA is activated. The collected sample will be sent to the Health Services Laboratory (HSL) for analysis.

At the end of the trial, if you give permission, leftover DNA material from your swab may be stored in an anonymised form for future research, with our research partners within the UK & EU. Our Research Partners sign agreements with us that specify and limit how they can use your data. We require our research partners to have strict privacy and security measures which are checked by us before we release a sample to them. Our Data & Sample Access Committee review such proposals and only give approval after a thorough review of the proposed use of the sample. Additionally, they would have to undergo separate research ethics applications for their proposed research.

Our Data & Sample Access committee will not approve the release and future use of stored samples for any research that might have the potential to identify you or have any disease implications for blood relatives.

If you change your mind at any point about the long-term storage of your leftover sample, please contact: trial@sola-diagnostics.com.

You can still take part in the trial and not agree to give permission for future use of your leftover sample.

If you do not agree for your leftover samples to be stored, they will be destroyed as soon as the lab analysis of your sample is complete.

Will my GP be informed if I take part in this study?

With your permission we will inform your G.P if you participate in this study. Results of the test will be shared with your G.P as part of standard of care practice.

You will have the option to view your test results, should you choose to, through your healthcare provider's app if the hospital site has this app provision in place. The clinical team will also write to you directly with your WID®-Easy test results.

What if I have a question or there is a problem?

If there is anything about the study you are not sure of, please ask a member of your care team at the hospital or speak with the researchers directly, Email: EASYCAREteam@nhs.net Telephone: 020 3447 6564

If you are unhappy about any aspect of the study and wish to make a complaint you can do this through the NHS complaints procedure. Your hospital will be able to give you information about how to do this. You can also contact the independent Patient Advice and Liaison Service (PALS) at your hospital , Telephone: 020 3447 3042
Email: uclh.pals@nhs.net. You can also contact the site hospital doctor responsible for this research, Email : EASYCAREteam@nhs.net

We don't anticipate any problems but if something does go wrong and you are harmed during the research due to someone's negligence, you may have grounds for legal action for compensation against the sponsor (Sola Diagnostics), although you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

If the harm is not due to anyone's negligence (for example, an unexpected side effect), you will still receive appropriate medical care and treatment through the NHS.

What will happen to the results of the study?

Once the trial is complete, results will be published in scientific journals. If the results are significant, they may be reported in the media. If the test proves to be effective and suitable for wider use, it may be adopted by the NHS to improve womb cancer diagnosis.

How will we use information about you?

We will need to use information from you and from your medical records and from the NHS Digital registries for this research project.

This information will include your:

- Initials
- NHS number
- Name
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Sola Diagnostics UK is the Sponsor of this research.

Sola Diagnostics UK is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- NHS Pathology laboratory - for analysing your sample
- UCL Partners - our research partners working on the participant questionnaire & 1:1 Interviews.
- Lindus Health - contract research organisation that will develop the research database and help with monitoring the trial, to ensure that the trial is being conducted properly.

National Cancer Registration and Analysis Service - to collect outcome data at 12 months, the team will link your data with this registry.

We will keep all information about you safe and secure by:

- Storing the research data without any identifiable personal information on a secure server following high standards of Information Security Standards.
- All staff involved in the research (clinical team and lab team) will have received training on how to keep your identifiable data safe and work to a high standard of Information Governance applicable to their respective NHS institutions.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- The data may be shared with our research collaborators with whose support the current test was developed.
- The sharing of this data will also facilitate the knowledge pool in women's health research

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Other research collaborators with the UK & EU, which include both academic institutions and commercial partners.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet. Further information can be found at **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to Sola Diagnostics: trial@sola-diagnostics.com

How will we use information about you after the trial ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 15 years. The study data will then be fully anonymised and securely destroyed.

Who is funding, carrying out and checking the research?

The research is funded by the National Institute for Health and Care Research (NIHR). It has been reviewed and given approval by Cambridge South Research Ethics Committee.

The Sponsor (Sola Diagnostics) is legally responsible for ensuring that the study is properly designed, conducted, and reported.
The Sponsor Representative acts on behalf of the Sponsor and is responsible for overseeing the day-to-day management of the study, ensuring that participant safety, privacy, and wellbeing are protected and making sure that the study follows all applicable ethical, scientific, and legal requirements.

- If you have questions about how the study is managed or who is responsible for ensuring it runs safely and correctly, you can contact the Sponsor Representative: Dr Sara Sleigh , trial@sola-diagnostics.com)

Alternatively, you can also contact the doctor responsible for this trial at your local hospital:

For questions relating to the study please contact:

Professor Davor Jurkovic Email: EASYCAREteam@nhs.net

Telephone: 020 3447 6564

Thank you for reading this Information Sheet and for considering participation